DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

February 21, 2002

WARNING LETTER
CIN-02-WL-12579

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Brian R. Browning, President
Medico Medical Equipment & Supplies, Inc.
72 North Rocky River Drive
Berea, Ohio 44017

Dear Mr. Browning:

The U.S. Food and Drug Administration conducted an inspection of your medical oxygen (compressed and liquid) transfilling operation at the above Berea, Ohio address, on January 30-31 and February 5, 2002. This inspection documented significant deviations from the current Good Manufacturing Practice regulations for drugs. These deviations cause your medical gases to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Specific deviations observed include:

1) Failure to test bulk incoming liquid medical oxygen upon receipt, prior to use in filling cryogenic Dewars.

2) Failure to establish appropriate written procedures and batch production records describing and documenting prefill, fill and postfill checks for cryogenic Dewars and cryogenic home units.

3) Failure to test new and/or repaired cryogenic vessels (Dewars and home units) for identity before distribution.

4) Failure to establish a formal quality control unit.

5) Failure to provide and document medical gas GMP training for each individual responsible for medical gas transfilling and distribution operations.

6) Failure to establish, maintain and make available for FDA review medical oxygen batch records for 8 of 12 months in the year 2000.

7) Failure to establish and follow appropriate calibration procedures for your oxygen test meter. There was no record of calibration for this meter from 6/15/01 to 10/14/01 during which time oxygen was transfilled. Calibration records do not document the calibration set point and records do not document that the calibration record was reviewed and approved for accuracy and completeness.

8) Failure to establish and follow appropriate equipment calibration procedures. There are no written procedures describing the frequency with which pressure/vacuum gauges and thermometers are to be calibrated. Calibration tags on pressure/vacuum gauges indicate these gauges were last calibrated 10/98 and were due for recalibration 10/99. Written procedures for scales used in transfilling state they are to be calibrated annually. Records indicate these scales were last calibrated in 6/99.

9) Failure to establish and follow adequate label control procedures in that there are no procedures for documenting receipt of drug labels and reconciling their distribution and use.

10) Failure to follow established expiration dating procedures. Written procedures state that medical gases transfilled into high pressure cylinders are to be assigned an expiration date of 5 years. Batch records show various expiration dates assigned to lots ranging from 2-5 years.

11) Batch records for compressed Oxygen USP lack written documentation (signatures and dates) showing the records were reviewed and approved for accuracy , completeness and suitability prior to release and shipment. Batch records do not document the daily zero check to verify appropriate functioning of the vacuum gauge.

The above described violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that you adhere to all current regulations applicable to your operations. Until these violations are corrected, Federal agencies will be informed that FDA recommends against award of contracts for affected products.

You should take prompt action to correct these violations. Failure to achieve prompt correction may result in regulatory action without further notice. These include seizure and/or injunction.

Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you are taking to correct these violations. Your response should explain each step you have taken to correct the noted violations, including steps taken to prevent recurrence of similar violations. Include any documentation showing these corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237-3097, to the attention of Charles S. Price, Compliance Officer. Any questions regarding this letter may be directed to Mr. Price at telephone (513) 679-2700 extension 165.

Sincerely,

Mary A. Woodcock for
Henry L. Fielden
District Director
Cincinnati District